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Diagnosing PIP breast implant failure: A prospective analysis of clinical and ultrasound accuracy☆

J.C. Mennie [a,*], O. Quaba [a,b], M. Smith [b], A. Quaba [b]

[a] Department of Plastic Surgery, Ninewells Hospital, Dundee, DD1 9SY, UK
[b] Spire Murrayfield Hospital, 122 Corstorphine Road, Edinburgh, EH12 6UD, UK

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Summary *Introduction:* The risk of Poly Implant Prosthesis (PIP) breast implant failure has been quantified by the Department of Health as 2—6 times greater than other brands. In the UK, removal of PIP breast implants is recommended when failure is suspected from patient history or clinical findings. Owing to conflicting reports of accuracy in current literature, ultrasound is not recommended as a routine investigation.

We aimed to evaluate the accuracy of patient history, clinical impression, and ultrasound at diagnosing implant failure in a large consecutive series of women against the reference standard. We aimed to provide evidence in response to current guidelines and help guide best practice.

Methods: All patients from January 2012—January 2013 who underwent PIP breast implant explantation at the Spire Murrayfield Hospital were prospectively evaluated. Operative findings were correlated to pre-operative results of patient history, clinical impression and ultrasound imaging. Sensitivity, specificity and accuracy were calculated with 95% confidence intervals.

Results: A total of 192 women who underwent 384 PIP implant explantations from January 2012 to January 2013 were included. Twenty-three patients (12.0%) reported a positive patient history pre-operatively. In 35 patients (18%), failure was pre-operatively diagnosed clinically. Intra-operatively, 80 implants (21%) in 63 women (33%) had failed. The sensitivity of patient history, clinical impression and ultrasound was 12%, 34%, and 91%, respectively. The specificity was 88%, 89%, and 97%, respectively. Ultrasound was 96% accurate at diagnosing PIP implant failure, whilst patient history and clinical impression were 63% and 71% accurate, respectively.

Conclusion: Ultrasound provides a far more reliable test of implant failure than patient history

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* Corresponding author. Tel.: +44 07875666980.
E-mail address: jomennie@doctors.org.uk (J.C. Mennie).

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or clinical impression. Considering the availability, cost and number of women in the UK with PIP implants, we would recommend high-resolution ultrasound be implemented as a routine investigation.

Introduction

Production of Poly Implant Prosthesis (PIP) silicone breast implants ceased in 2010 following exposure from the French regulator (AFSSAPS) regarding the safety of the implants.[1] The UK regulator, Medicines and Healthcare Products Regulatory Agency (MHRA), swiftly followed in the French recommendation to withdraw PIP implants from the market. An estimated 47,000 women however, had already received PIP implants in the UK, both in the public and private sector.[2] Such controversy evoked a strong focus of media attention.[3] Reports revealed industrial grade, rather than medical grade silicone, had been used in production.[4] Additional concerns regarding shell integrity and failure rates soon emerged.[5]

The risk of failure in PIP breast implants has since been quantified as 2—6 times greater than other brands of silicone breast implants by the Department of Health's PIP working group.[6] In our previous study we reported a PIP implant failure rate of 35.2% per patient in 338 patients, and 21.3% per implant.[7] Berry et al. subsequently reported a device failure rate of 36.5% in 326 implants.[8]

Currently the UK regulatory agency does not call for routine removal of PIP breast implants. If failure is suspected from patient history or clinical exam, the Specialty Surgical Associations advocate explantation.[9] Scanning is outlined as an option in cases of clinical doubt, or when patients are uncertain as to whether to have their implants removed, but not as a routine investigation. Whilst current literature suggests MRI is more sensitive than ultrasound in detecting implant failure,[10,11] the cost and waiting times are such that The Royal College of Radiologists advise ultrasound should be the first imaging modality of choice.[12,13] The Royal College of Radiologists however also highlight a need for caution in interpretation of such ultrasound results due to conflicting small study reports of accuracy in the current literature.

Previously reported ultrasound sensitivity and specificity has ranged from 50% to 97% and 76%—93% respectively.[14—18] Interpretation of these previous reports is difficult however due to several limitations including study design, cohort numbers and bias. In a meta-analysis by Song et al., a pooled ultrasound sensitivity and specificity of 61% and 76%, respectively, was found.[16] However 66% of studies included in this meta-analysis were solely from symptomatic patients. Furthermore details regarding explantation were inconsistently reported. Ikeda et al.'s study of 30 symptomatic patients found an ultrasound sensitivity of 67% and specificity of 92%.[17] In their study though, only 16 patients proceeded to surgery. Hold et al. reported the lowest ultrasound sensitivity of 50% in a retrospective review of 34 symptomatic patients.[18] Again, only 14 patients proceeding to surgery. Berry et al. most recently reported the highest accuracy in a cohort of PIP patients of 92.9%.[8] Unfortunately however only 51% (85 patients) of their cohort who did have an ultrasound scan, had results confirmed at surgery.

With many of these prior studies focusing on small cohorts of symptomatic patients, the current evidence has to be interpreted cautiously. Studying only symptomatic patients introduces a spectrum bias.[19] Furthermore, it is now well accepted that many implant ruptures are infact silent, and this has to be considered when calculating the diagnostic accuracy of ultrasound.[20] Our previous work reporting on failure rates unfortunately suffered significant selection bias, as only 49% of the total cohort explanted were referred for pre-operative ultrasound.[7] To truly assess diagnostic accuracy and avoid clinician selection bias, a consecutive cohort of patients should be tested. The overriding limitation of previous studies however, is the lack of confirmation of negative results. To accurately assess the diagnostic ability of ultrasound, results need to be compared to the reference standard testing; explantation surgery. If reference standard testing is not undertaken, a verification bias is introduced as false negative results are not confirmed.[21]

The advances in ultrasound technology also need to be revisited, specifically the introduction of high-resolution ultrasound. Despite a small study, Bengston recently provided encouraging early clinical results indicating an excellent correlation between high-resolution ultrasound and MRI in the diagnosis of breast implant failure.[22] Many of the rates of accuracy previously reported pertain to older studies, without high-resolution technology.

Given the limitations of previous literature, the need for further evaluation of the accuracy of ultrasound to detect PIP implant failure is clear. In the context of the current Department of Health and Joint Speciality Surgery Association PIP implant guidelines, correlation of clinical accuracy also needs quantified.[6,9] Our previous study lacked such clinical correlation. Furthermore in our previous work we included patients who consulted with or were operated on by other surgeons.[7] When assessing clinical accuracy, the inclusion of multi-surgeon data can lead to a reporting bias and affect the validity of results.

The aim of our study was to prospectively evaluate the accuracy of patient history, clinical impression and ultrasound in diagnosing PIP implant failure in a single-surgeon cohort. The widespread publicity surrounding PIP implants, combined with the policy of our institution to proactively recall all patients, and underwrite the costs of implant exchange, presented a unique opportunity to evaluate